REMARKS

Entry of the foregoing and favorable reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, pages 78 and 79 of the specification have been amended to correct the error in Table 1, since it was an obvious error that Sequence No. 7 was inadvertently missing in the numbering of this Table. Claims 1-6, 12-16, 20, 21, 24 and 62 have been amended as per the statement on page 5 of the Office Action under the heading "Allowable Subject Matter." Other claim amendments have been made for purposes of complying with the MPEP regarding proper language for dependent claims, correcting improper multiple dependencies, changing "containing inserted therein" or "containing" to "comprising", providing clear antecedent basis and correcting typographical errors. Applicants reserve their right to file a divisional application directed to the non-elected inventions. Applicants submit that no new matter has been added via this amendment.

Therefore, entry of the amendment is requested because it places the claims in condition for allowance, or at the very least, simplifies issues for purposes of appeal.

Pages 78 and 79 of the specification have been amended. Specifically, Table 1 has been amended to include SEQ ID NO:7, which was inadvertently omitted from the numbering in this table. This Table is now consistent with the description of the specification at least on page 12. Applicants submit that this error is obvious, especially in view of the missing SEQ ID NO:7 and in view that SEQ ID NO:39 had two different inconsistent entries in the Table. Thus, no new matter is added via this amendment.

Claims 17-19 have been objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

As suggested by the Examiner, claims 17 to 19 have been amended by including the recitation "*wherein the nucleic acid is inserted*" added. These claims are now multiply dependent upon claims 12-16 and refer to a recombinant vector, such as a pACTIIst plasmid, a pAS2ΔΔ plasmid, pT25, pKT25, pUT18, pUT18C, pP6 or pB5, in which a nucleic acid of the invention has been inserted.

Claim 24 has been objected to because of informalities. The expression "*two nucleic acid*" has been corrected and the plural "acids" is now recited.

Claims 1-6, 12-21, 24 and 62 have been objected to because they include nonelected species.

Claims 1-6 have been amended to recite the elected amino acid sequence SEQ ID NO:20. Likewise, claim 24 has been amended to recite a set of two nucleic acids encoding polypeptides of sequences SEQ ID NOS:58 and 132. Other claims have been amended to recite the elected nucleic acid (SEQ ID NO:58).

Claims 17 and 19 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. For the following reasons, this rejection is respectfully traversed.

The Examiner maintains that the specification does not in any way point to the prior art which allegedly teaches one how to make the plasmids pASΔΔ, pACTIlst, or the starting material used for making pP6, and the record does not establish that the disclosure in the prior art is sufficient to render the plasmids both known and readily available to the public.

However, as previously explained, at the time the claimed invention was made, the skilled artisan was well aware

of how to make these plasmids. A patent application need not recite that which is well known in the art at the time of filing of the application. *See, e.g., S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1371, 59 USPQ2d 1745, 1749 (Fed. Cir. 2001).

Considering that the creation of vectors was common knowledge and scientifically predictable for the one skilled in the art at the time of filing the present invention, Applicants submit that it is unnecessary to deposit the plasmids or to specifically describe in the specification how to make these vectors. The documents submitted by the Applicant in the response dated March 4, 2004, relate to such technology. The preparation of the plasmids recited in claims 17-19 would not have been involved undue experimentation.

More specifically, WO 99/42612 filed by the same inventor, on page 9, lines 23-25 and in Figure 7, shows that pAS2ΔΔ is derived from pAS2 plasmid, publicly sold by Clonetech, as follows: the CYH2 gene was deleted by partial *Eco*RV digestion followed by a self-ligation, the HA epitope was then deleted by removing the *Eco*RI-*Nde*l fragment. Either is depicted in this application the way to prepare pACTIIst, on page 9, lines 26-27 and in Figure 8, starting with pACTII, plasmid described in Durfee, *et al.*, Genes Dev. 7:555-569 (1993), and adding three stop codons before the *Xho*l site of the polylinker.

The preparation of the pB6 plasmid is depicted in the specification (pages 66-67) by replacement of the *Spe*1/*Xho*1 fragment of pGAD3S2X with a given double stranded oligonucleotide. Such a modification was within the knowledge of the one skilled in the art: the starting material, available to the public prior the filing date (J. Biol. Chem. *272*, issue 40, 26026-26035 (1998), plasmid available from M. Cognet-Vasseur, INSERM U129, Paris, France), and the succinct protocol (page 66: *1.A.3 vector preparation,* page 67: *1.A4 ligation*

between vector and insert of genomic DNA) would have enabled one skilled in the art to prepare the recited plasmid.

The Examiner also maintains that since the specification does not provide any information about how to make the plasmids pT25, pKT25 or pUT18C, and that Figures 5-7 do not indicate the extent of the differences from the plasmids they were derived from, these recited plasmids lack enablement.

Plasmid pT25 is a derivative of pACYC184 that encodes the T25 fragment of CyaA (amino acids 1-224) in frame with a multicloning site sequence, under the control of the *IacUV5* promoter as it is depicted in Ladant, *et al.*, Proc. Natl. Acad. Sci. USA *95*:5752-5756, (1998) (page *5752, materials and methods*). This publication indicates that plasmids were provided by the inventor of the present application (page *5756*, underneath comments). Moreover, the attention of the Examiner is drawn to Figure 6 of the present application and the fact that pACYC184 plasmid is commercially available at Fermentas or DSMZ.

As illustrated in Ladant, *et al.* J. Bacteriol., Dec. 2000, pp. 7060-7066, plasmid pKT25 is a derivative of the low-copy-number vector pSU40 (harboring a kanamycin resistance selectable marker) that expresses the N-terminal (T25) fragment (codons 1 to 224) of cyaA under the transcriptional and translational controls of the *lacZ* gene. It was constructed by subcloning a 1,044-bp *Hind*III-*Eco*RI fragment from pT25 into pSU40 linearized with *Hind*III and *Eco*RI and then by deleting a 236-bp *Nhe*I-*Hind*III fragment. Thus, the preparation of this plasmid is known in the art. Aside from the detailed illustration in Figure 7 of the present application, the pSU40 plasmid is described in Bartolome, *et al.*, Gene *102*:75-78 (1991). Thus, one skilled in the art would have been enabled to prepare the pKT25 plasmid.

As illustrated in Figure 5 of the present application, pUT18C differs from pUT18 only in the position and sequence of MSC: for pUT18, the MSC position is at the beginning of the T18 with a specific sequence, and at the end of the T18 for pUTC18C with a specific sequence. Therefore, no undue experimentation would be required by one skilled in the art to make and use the claimed invention with the pUT18C plasmid.

In the specification, e.g., page 68 and Figures 2 and 12, the preparation of the pB5 plasmid is depicted. It is prepared by replacing the *NcoI/SAII* polylinker fragment of pAS2ΔΔ (see preparation above) with a double-stranded oligonucleotide of given sequence (SEQ ID NO:154). Here again, one skilled in the art, on the basis of such information and of his/her own skills in the plasmid preparation, would have been enabled to make and use the pB5 plasmid.

Thus, as demonstrated above, in view of the teachings in the prior art as well as the description in the present specification, the skilled artisan would have been enabled to make and use the plasmids recited in claims 17-19 without undue experimentation. A deposit of these plasmids is therefore not necessary for their reproducibility or to otherwise comply with the enablement requirement of § 112, first paragraph.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

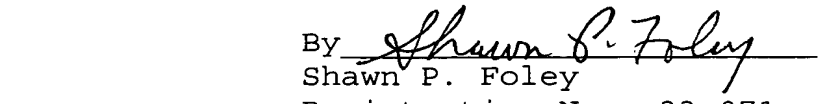
As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: September 29, 2004

Respectfully submitted,

By 

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